DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 2, 2016

Biomet Manufacturing Corporation
Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
56 East Bell Drive
Warsaw, Indiana 46580

Re: K121183
Trade/Device Name: Comprehensive® Reverse Shoulder – E1® Polyethylene Claims
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, PAO, KWS
Dated: April 13, 2012
Received: May 8, 2012

Dear Ms. Beres:

This letter corrects our substantially equivalent letter of July 26, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121183

Device Name: Comprehensive® Reverse Shoulder – E1® Polyethylene Claims

Indications For Use:
The Comprehensive® Reverse Shoulder is indicated for use in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.

The Comprehensive® Reverse Shoulder is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.

Glenoid components with Hydroxyapatite (HA) coating applied over the porous coating are indicated only for uncemented biological fixation applications. The Glenoid Baseplate components are intended for cementless application with the addition of screw fixation.

Interlok® finish humeral stems are intended for cemented use and the MacroBond® coated humeral stems are intended for press-fit or cemented applications. Humeral components with porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.

Prescription Use ___X___ AND/OR Over-The-Counter Use __NO___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121183

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JUL 26 2012

BIOMET
MANUFACTURING CORP.

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

SUBMITTER INFORMATION	
Name	Biomet Manufacturing Corp.
Address	56 East Bell Drive Warsaw, IN 46582
Phone number	(574) 267-6639
Fax number	(574) 371-1027
Establishment Registration Number	1825034
Name of contact person	Patricia Sandborn Beres Senior Regulatory Specialist Biomet Manufacturing Corp.
Date prepared	June 14, 2012
NAME OF DEVICE	
Trade or proprietary name	Comprehensive® Reverse Shoulder - E1® Polyethylene Claims
Common or usual name	Shoulder Prosthesis
Classification name	Shoulder joint, metal/polymer, semi-constrained, cemented prosthesis
Classification panel	Orthopedics
Regulation	21 CFR 888.3660
Product Code(s)	KWS, PAO
Legally marketed device(s) to which equivalence is claimed	Comprehensive® Reverse Shoulder System – K080642 Comp. Reverse Shoulder - E1® Humeral Bearings – K113121
Reason for 510(k) submission	Claims language
Device description	The Comprehensive® Reverse Shoulder is intended for total shoulder replacement in a reverse shoulder configuration. Unlike traditional total shoulder replacement, a reverse shoulder employs a ball for articulation on the glenoid side of the joint and a polyethylene bearing surface on the humeral side of the joint. This device configuration increases the lever arm of the deltoid muscle bundle to provide stability and the ability to raise the arm. This is especially useful in cases where a patient has a non-functioning rotator cuff which severely limits traditional joint replacement options.
Intended use of the device	Shoulder Replacement

Mailing Address:
P.O. Box 587
Warsaw, IN 46581-0587
Toll Free: 800.348.9500
Office: 574.267.6639
Main Fax: 574.267.8137
www.biomet.com

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

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Indications for use	The Comprehensive® Reverse Shoulder is indicated for use in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary. The Comprehensive® Reverse Shoulder is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency. Glenoid components with Hydroxyapatite (HA) coating applied over the porous coating are indicated only for uncemented biological fixation applications. The Glenoid Baseplate components are intended for cementless application with the addition of screw fixation. Interlok® finish humeral stems are intended for cemented use and the MacroBond® coated humeral stems are intended for press-fit or cemented applications. Humeral components with porous coated surface coating are indicated for either cemented or uncemented biological fixation applications.
SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE HUMERAL BEARING COMPARED TO THE PREDICATE	
The devices contained in this 510(k) are identical in material, dimensions, and attachment methods to the devices contained in the predicate Comprehensive® Reverse Shoulder System 510(k) submissions, K080642 and K113121	
PERFORMANCE DATA	
Summary Of Non-Clinical Tests Conducted For Determination Of Substantial Equivalence	
Environmental Stress Cracking Testing	
Small punch Testing	
Tensile Testing per ASTM F648	
Summary of Clinical Tests Conducted for Determination of Substantial Equivalence and/or of Clinical Information	
No clinical data submitted	
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA	
No clinical data was necessary for a determination of substantial equivalence. The results of testing indicated the material performed within the intended use, did not raise any new safety and efficacy issues and were found to be substantially equivalent to the predicate devices.	

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CLAIMS FOR E1® ANTIOXIDANT INFUSED TECHNOLOGY*

Claim 1:
E1® Antioxidant Infused Technology prevents oxidative degradation of polyethylene. Environmental stress crack testing was conducted by cyclically loading GUR1020 and GUR1050 E1® test specimens in an air atmosphere maintained at 80°C for 5 weeks. Testing was completed per the literature (Nabar, Sean, et al. Transactions of the 54th Annual Meeting of the ORS, Poster No. 1684). E1® specimens showed no evidence of environmental stress cracking and infrared spectroscopy showed no detectable oxidation in the loaded or unloaded samples (oxidation indices <0.1). E1® samples were machined from either GUR1020 or GUR1050 isostatically compression molded UHMWPE crosslinked with 100 kGy gamma irradiation under argon, doped with α-tocopherol, and subsequently gamma sterilized (25-40 kGy) in Argon. *Bench testing is not necessarily indicative of clinical performance.*

Claim 2:
E1® Antioxidant Infused Technology protects polyethylene from oxidation and cracking during environmental stress crack testing. Environmental stress crack testing was conducted by cyclically loading test specimens in an air atmosphere maintained at 80°C for 5 weeks per the literature (Nabar, Sean, et al. Transactions of the 54th Annual Meeting of the ORS, Poster No. 1684). GUR1050 E1® specimens ran head to head with GUR1050 gamma sterilized (25-40kGy in argon) polyethylene and sequentially crosslinked and annealed polyethylene (GUR 1050 barstock, 33kGy gamma irradiated in air, annealed at 130C in air and repeated for a total dose of 99kGy and machined into final part geometry). GUR1020 E1® specimens ran head to head with GUR1050 direct compression molded polyethylene that was gamma sterilized (25-40kGy) in argon. The E1®material was the only material tested that showed no evidence of environmental stress cracking or fracture and no detectable oxidation (oxidation indices <0.1) in the loaded and unloaded samples using infrared spectroscopy. Both gamma sterilized and sequentially crosslinked and annealed polyethylene showed evidence of increased oxidation and cracking or fracture during environmental stress crack testing. E1® samples were machined from either GUR1020 or GUR1050 isostatically compression molded UHMWPE, crosslinked with 100 kGy gamma irradiation under argon, infused with vitamin E, and subsequently gamma sterilized (25-40 kGy) in Argon. *Bench testing is not necessarily indicative of clinical performance.*

Claim 3:
E1® Antioxidant Infused Technology maintains the mechanical strength of conventional UHMWPE under small punch testing. Small punch testing per ASTM F2183 was conducted for the E1® GUR1050 material and the E1® GUR1020 material. The E1® GUR1050 material was compared to GUR1050 gamma sterilized in argon isostatic compression molded (ICM) UHMWPE and the E1® GUR1020 material was compared to GUR1050 gamma sterilized (25-40kGy) in argon direct compression molded (DCM) UHMWPE. The ultimate load for the E1® GUR1050 material and the GUR1050 ICM

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material are 105±5.5N and 75.4±5.3N respectively. The ultimate load for the E1® GUR1050 material and the DCM control material are 97.2±6.4N and 86.6±7.5N respectively. The E1® materials had ultimate loads greater than that of the ICM and DCM control. These differences were statistically significant ($p<0.001$ for all comparisons). E1® samples were machined from either GUR1020 or GUR1050 ICM UHMWPE, crosslinked with 100 kGy gamma irradiation under argon, infused with vitamin E, and subsequently gamma sterilized (25-40 kGy) in Argon. *Bench testing is not necessarily indicative of clinical performance.*

Claim 4 :
E1® Antioxidant Infused Technology maintains mechanical strength after accelerated aging. There was no significant decrease ($P>0.05$) in ultimate load , ultimate tensile strength, or yield strength after accelerated aging for either the E1® GUR1050 or the E1® GUR1020 material. Ultimate load was measured by small punch testing per ASTM F2183; ultimate tensile strength and yield strength were measured by tensile testing per ASTM D638; Accelerated aging was performed per ASTM F2003 (70°C and 5 atm of oxygen for 14 days). The ultimate load for the E1® GUR1020 material before and after accelerated aging was 97.2±6.4N and 100.0±5.0N respectively. The ultimate tensile strength for the E1® GUR1020 material before and after accelerated aging was 45.8±1.6 and 46.1±2.9 MPa respectively. The yield strength for the E1® GUR1020 material before and after accelerated aging was 22.6±0.2 and 22.8±0.3 MPa respectively. The ultimate load for the E1® GUR1050 material before and after accelerated aging was 105.0±5.5N and 115.0±3.2N respectively. The ultimate tensile strength for the E1® GUR1050 material before and after accelerated aging was 43±3 and 43±2 MPa respectively. The yield strength for the E1® GUR1050 material before and after accelerated aging was 24.2±0.2 and 24.4±0.2 MPa respectively. E1® samples were machined from either GUR1020 or GUR1050 isostatically compression molded UHMWPE, crosslinked with 100 kGy gamma irradiation under argon, infused with vitamin E, and subsequently gamma sterilized (25-40 kGy) in Argon. *Bench testing is not necessarily indicative of clinical performance.*

Note:** ***E1® Antioxidant Infused Technology may be used interchangeably with any of the following: E1® Antioxidant Infused Bearings, E1® Antioxidant Infused Material, E1® material, E1® technology, E1® bearings, E1® liners, E1® acetabular liners, E1® Humeral Bearings and E1®